K130067

MAY 08 2014

Applicant

mRNA appliance™
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Official Contact:	Colette Cozean, PhD (949) 855-2885; ccozean@cox.net
Proprietary/Trade Name:	mRNA appliance™
Common/Usual Name:	Dental Device – Anti Snoring/Obstructive Sleep Apnea Device
Classification Name:	Anti-Snoring/Obstructive Sleep Apnea Device, Jaw-position Device
Proposed Product Code:	LRK
Predicate Devices:	SomnoMed MAS R x A, K050592 DynaFlex Anti-Snoring and Sleep Apnea Devices, K103076 Adjustable Dorsal Intraoral Device, K130130

Device Description

The mRNA appliance is an intraoral device used for treating snoring and mild to moderate sleep apnea, functioning as a mandibular repositioner and acting to increase the patient's pharyngeal space to improve the ability to exchange air. It consists of two customized trays that fit over the upper and lower teeth. An adjustment mechanism enables the device to be customized for each patient.

Scientific Principles

During sleep, the muscles in the tongue and back of the throat relax, which can cause them to sag and narrow the airway. Airflow through a narrow airway is the cause of snoring. When this narrowing of the airway is severe, it results in Obstructive Sleep Apnea (OSA), where the airway actually closes. Upon closure, the brain detects the lack of oxygen and wakes the body to draw breath, disturbing sleep.

Device Function

The mRNA appliance is a customized oral device featuring both lower (optional) and upper interlocking trays. These trays prevent the collapsing of the tissues in the back of the throat and preserves the airway.

Studies have shown that customized oral devices that function by increasing the patency of the airway show comparable efficacy to continuous positive airway pressure (CPAP) devices, considered the gold standard of treatment for OSA (*Oral appliance therapy in Obstructive Sleep Apnea-Hypopnea syndrome - A clinical study on therapeutic outcomes* Hoekema A PhD thesis, University Medical Centre Groningen Department of Oral and Maxillofacial Surgery. pp 110, 2007). On the basis of these studies, use of oral devices has been recommended by the American Academy of Sleep Medicine for patients with mild or moderate OSA, or for those with severe OSA who are unable to tolerate the CPAP device.

The mRNA appliance consists of upper and lower interlocking, customized trays. The mRNA appliance is customized on models of the patient's teeth, using standard orthodontic acrylics and standard orthodontic wires for clasps and retention. The mRNA appliance allows for interlocking of the upper and lower trays; the mandibular position may be adjusted antero-posteriorly (AP), transversely (TV), as well as permitting adjustments of the vertical dimension of occlusion (VDO). The interlocking of the upper and lower trays to permit adjustments in the vertical dimension is the primary unique feature of this design.

Intended Use

Indication for Use: To reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Target Population: Adult patients, over 18 years of age, with snoring and mild to moderate obstructive sleep apnea.

Environment of Use: Fitting of the mRNA appliance in the dental office for patient use at home.

Substantial Equivalence to Predicate Devices

The mRNA is being compared to the following predicate devices: SomnoMed (K050592), Dynaflex (K103076), and Adjustable Dorsal (K130130).

- Indication for Use: All devices are indicated "to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.
- Design and Function: All devices are customized and fitted to the patient's teeth. The wire and flange adjustment mechanism employed by the mRNA device is similar to the interlocking lugs and fins used in the SomnoMed MAS RxA and the DynaFlex devices. As with the predicate devices, the mRNA device functions by preventing the retruding of the mandible during sleep to obstruct the airway. The difference in functionality between the devices is the method in which the customized trays engage one another and the adjustability of the device. The mRNA allows for 2 additional degrees of freedom in the adjustment of the upper and lower appliances due to a flange and acrylic slot with a screw adjustment. The mRNA contains an acrylic slot on the upper appliance and a wire vertical flange on the lower appliance that engage each other

providing advancements of the lower component in 1 mm increments via a screw mechanism. An optional table can also increase the vertical height of the mRNA.

- Mechanism of Action: All devices cause mandibular repositioning, acting to increase the patient's pharyngeal space to improve the ability to exchange air during sleep. The mandible position is adjusted by the dentist using orthodontic expansion screws in all devices.
- Composition and Construction: Professional, industry-standard dental acrylics, stainless steel alloy orthodontic wires, and orthodontic adjustment screws are used in the mRNA appliance and the SomnoMed and DynaFlex devices. The Adjustable Dorsal device is made using the same MMA from Lang Dental. Unlike some of the devices, there is no coloring agent in the mRNA. The mRNA uses stainless steel alloy orthodontic wire and beta titanium arch wire used in similar dorsal devices. The manufacturing procedure for the mRNA is similar to that of the Somnomed appliance. The only significant difference is to place expansion screw and beta-titanium 3D-axial springs as required for adjustability and the optional occlusal table.
- Shelf Life, Storage Conditions and Cleaning Instructions: All products are provided non-sterile with identical shelf lives. The cleaning instructions for mRNA are the same as those for the Adjustable Dorsal Device.
- Risk Analysis: All devices can cause intraoral gingival, palatal or dental soreness. Patients with loose teeth or advanced periodontal disease are contraindicated from use of the appliance. mRNA, like the other devices, have minimal material in the anterior of the appliance to reduce obstruction of oral breathing. There is an additional flange in the mRNA, but it prevents less than 1% of air flow. Risk analysis of the flange showed that the wire used can easily tolerate the additional weight it assumes. Patients with central sleep apnea or severe respiratory disorders are contraindicated from use of the device. General tooth movement may occur with the mRNA as with the predicate devices over time. As with the predicate devices, breakage of acrylic and wire components may occur with excessive force.
- Biocompatibility: The mRNA appliance consists of 5 components, all of which are used in predicate devices: Lang MMA monomer, Lang MMA polymer, stainless steel alloy orthodontic wire, orthodontic expansion screws and beta titanium arch wire. There are no new biocompatibility risks when comparing the mRNA and the predicate devices.

Non-clinical Testing

The materials used in the predicate devices are identical to those in the subject, as the materials are provided by the same manufacturer. The manufacturing processes between the predicate devices and subject device are identical and these are the reasons biocompatibility testing was not included in the submission. A risk analysis was performed, which considered soreness, obstruction of breathing, tooth movement, and breakage. The product was compared to predicate devices in each area to show the risks were equivalent to the predicate devices. An analysis of the tensile strength of the flange was also reported.

Clinical Testing

No animal or clinical testing is included.

Conclusion

In conclusion, the only difference in mRNA from the predicate devices is the mRNA allows for 2 additional degrees of freedom in the adjustment of the upper and lower appliances due to a flange and acrylic slot described above with a screw adjustment. An optional occlusal table can also increase the vertical height of the mRNA. These changes do not affect the substantial equivalence of the device, because: i) they do not change the indication for the device, ii) they do not change the mechanism of action, iii) they do not substantially change the construction or employ any new raw materials, and iv) they do not elevate the risk. Non-clinical testing supports this conclusion. No biocompatibility testing was included because the materials used in the mRNA are used in the predicate devices. A risk analysis was performed. The only new risk with the mRNA is the weight seen by the flange, which is order of magnitude less than the tensile strength of the flange. No animal or clinical testing is required, because the changes in the device only provide additional adjustability of the device to the move and do not introduce any new clinical risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 20, 2014

BioModeling Solutions, Limited Liability Company
c/o Colette Cozean, PhD
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Re: K130067
Trade/Device Name: mRNA Appliance™
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: April 11, 2014
Received: April 16, 2014

Dear Dr. Cozean:

This letter corrects our substantially equivalent letter of May 8, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K130067

Device Name: mRNA appliance™

Indications for use:

1. For the treatment of snoring and mild to moderate obstructive sleep apnea in adults.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael E. Adjodha -S
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